

Claims

1. A process to minimise loss of one or more of the components through adhesion to equipment surfaces, which comprises addition of two or more components to a container in a stepwise manner.

2. A process for adding components to a multicomponent pharmaceutical formulation for inhalation comprising a step wise addition of the components to a container in order to minimize or eradicate losses due to adhesion of component to the container surface.

3. A process according to claim 1 or 2 in which the component of largest mass is added first.

4. A process according to claim 2 or 3 in which the formulation components are active drug substances.

5. A process according to any one of claims 2 to 4 in which the formulation is for a pressurized metered dose inhaler.

6. A process according to claim 4 or 5 in which the active drug substances are budesonide and formoterol, a pharmaceutically acceptable salt or solvate thereof, or a solvate of such a salt.

7. A process according to any one of claims 4 to 6 in which the active drug substances are budesonide and formoterol fumarate dihydrate.

8. A process according to claim 7 in which the molar ratio of the budesonide to the formoterol fumarate dihydrate is from 2500:1 to 1:1.

9. A pharmaceutical formulation prepared according to the process defined in any one of claims 2 to 8.

10. A formulation according to claim 9 which is in the form of a suspension.

11. A formulation according to claim 10 in which the drugs are suspended in one or more HFA propellants.

12. A formulation according to claim 11 in which the HFA propellants are HFA 134a or
5 HFA 227 or a mixture thereof.

13. Use of a formulation according to any one of claims 9 to 12 for the treatment or prophylaxis of asthma or COPD.

10 14. A method of treating asthma or COPD which comprised administering to a patient in need of such treatment a formulation according to any one of claims 9 to 12.